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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/944,234	10/06/1997	VINCENT BRYAN	A8038	1173

7590 07/20/2006

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WASHINGTON, DE 20037-3213

EXAMINER
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NGO, LIEN M

ART UNIT	PAPER NUMBER
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3754

DATE MAILED: 07/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

08/944,234

Applicant(s)

BRYAN ET AL.

Examiner

LIEN TM NGO

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 4 and 8-12 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 126, 127 and 129 is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) 34, 91 and 108 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Continuation of Disposition of Claims: Claims pending in the application are 1-28, 30-35, 37-50, 52-57, 59-61, 67-71, 73-76, 78-85, 87-92, 94-97, 100-102, 104-109 and 111, 114 -138 .

Continuation of Disposition of Claims: Claims rejected are 1-3, 5-7, 13-28, 30-33, 35, 37-50, 52-57, 59-61, 67-71, 73-76, 78-85, 87-90, 92, 94-97, 100-102, 104-107, 109, 111, 114 -125, 128 and 130-138 .

### DETAILED ACTION


1. In view of the Appeal Brief filed on 3/24/06, the final rejection dated 3/31/05 has been withdrawn and PROSECUTION IS HEREBY REOPENED. Upon further consideration, the objection to the specification under 35 U.S.C 132 and the rejection of claim 131, 134 and 137 under 35 U.S.C. 112, first paragraph are no longer appropriate and withdrawn in favor of the new ground rejections made as set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

  
Henry J. Recla  
Supervisory Patent Examiner  
Group 3700

***Claim Objections***

2. Claims 39, 40 and 94-96 are objected to because of the following informalities:

Claims 39 and 40 are objected as depending from canceled claim 36.

Claims 94-96 are objected as depending from canceled claim 93

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 39, 40, 81, 95, 96, 130, 135 and 133 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to claims 39, 40, 81, 95 and 96, "said at least two milling surfaces" lacks antecedent basis.

In regard to claims 130 and 135, "the head" (line 8) lacks antecedent basis. On page 4, paragraph 25, Applicants' specification states, "The drill head 20 generally comprises a form cutter portion 22, drive means 24, and attachment means 26." On page 5, last sentence, the specification recites, "Because of its profile, the drill head 20 of the present invention can fit in the narrow space between two opposing vertebral bodies in the cervical spine of a patient. " Claims 130 and 135 are indefinite in that it is

uncertain as to what structure previously recited in the claims is being referred to as "the head".

In regard to claim 133, based on the excerpts from the specification identified above, it appears that lines 8-10 are redundant to lines 3-7 which renders the claim indefinite. If not, then the claim is indefinite as to the structure in the specification that corresponds to the "means plus function" limitation.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 5-7, 13, 14, 18-28, 30-33, 35, 37-50, 52-57, 59-61, 67-71, 73-76, 78-85, 87-90, 92, 94-97, 100-102, 104-107, 109, 111, 114 –125, 128 and 130-138 are rejected under 35 U.S.C. 102(b) as being anticipated by Scheicher (4,197,645) as evidence by Michelson (6,080,155) or Kuslich et al. (5,489,308).

In judging the propriety of this rejection, it has been reformatted in light of Applicants' arguments in the appeal brief that the Examiner has not fully developed her prima facie case of anticipation. In so doing, the Examiner is relying on the extrinsic evidence presented in the Michelson and Kuslich, et al. references in support of the fact that the drill assembly of Scheicher is inherently capable of being used to bore holes in adjacent vertebral bodies in the manner claimed by Applicant. Exploring these extrinsic

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teachings, attention is first directed to figures 37–41 in the Michelson reference which illustrates horizontally oriented overlapping holes drilled into and between adjacent vertebral bodies for the purpose of inserting a complementally shaped implant.

Referring to figure 24 of the Kuslich, et al. reference, the extrinsic evidence reveals that it is also desirable to drill vertically oriented holes into and between adjacent vertebral bodies for the purpose of inserting a complementally shaped implant such as that illustrated in figures 20 and 21. The issue then remains as to whether the drill assembly of Scheicher is “inherently capable” of drilling such adjacent bore holes within the environments of the Michelson or Kuslich, et al., i.e., the spinal column.

“To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities of possibilities. The mere fact that a certain thing may result from a set of circumstances is not sufficient.” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

“In relying on the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

Further reference for the principles of inherency are found in the MPEP section 2112.

As illustrated in figures 1, 2 and 4 of the Scheicher reference, there is no doubt that the shape of the bore holes match those of the Michelson and Kuslich, et al. bore holes. Although the preferred environment in which the drilling assembly is used as disclosed by Scheicher is the dental field, such is not so limited. As disclosed in column 1, lines 10-15, the Scheicher reference states " The designation "bone drill" or "bone milling cutter" is meant to include all drills or cutters with which, in the field of humans or veterinary medicine, including the dental field, material can be removed from teeth, bones, and bone-like tissue, as well as from corresponding substitute materials."

To justify that the drill sizes of the Scheicher assembly are about the same or similar sizes necessary to drill holes between vertebral bodies, attention is first directed to column 3, lines 45 –58 and column 4, lines 11-14 of the Kuslich, et al. reference where it is recognized that various size implants are used based on the particular individual being treated. To give some dimensional parameters, the L-5 vertebra of a typical male patient is defined as requiring an implant having a diameter of about 0.5 inches. However, the Scheicher reference emphasizes that the dimensions of selected implants are relative. (See columns 4 and 5, the bridging paragraph). Referring to the Scheicher reference, it is most apparent that the drill assembly can be used with a single drill bit or a combination of drill bits. (See column 7, lines 11-35). As pointed out in column 2, lines 38-45, the drill head cutters can be of varying length, varying diameter and varying character. In column 9, lines 45-50, Scheicher discusses that when the bone drill is used for the insertion of dental implants, the cutting heads can have a lengths about 10-25 mm, and a diameters about 2-8 mm. When using a combination of



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drill heads as in figure 1-4, the Scheicher reference discloses that the axes of the drill heads can be spaced apart anywhere from 2.5 – 10 mm. If so, the diameter of each drill head would be a little less than 10 mm judging from the overlap shown in the figures.

In any event, from all the extrinsic evidence extracted from the Michelson and Kuslich et al. references, it is the Examiner's position that the drill heads of the Scheicher drill assembly are certainly within the ranges of sizes substantially, if not exactly, necessary for drilling holes within the spinal column for spinal implants, thus fulfilling the technical reasoning necessary to show that the Scheicher drill assembly is "inherently capable" of being used as claimed by Applicant.

Regarding to claim 2, the cutters of Scheicher are convex in the longitudinal direction.

Regarding to claim 3, the Scheicher device includes beveled gears 37 and 39 (figs.13-18).

Regarding to claim 21, the axis of elongated housing 1 of Scheicher is transverse to the axis of the rotary cutter.

Regarding to claim 24, the cylindrical prosthetics of Michelson and Kuslich have a convex outer cutter surface and concave inner surface.

Regarding to claims 53, 54, 81, 96, 118 and 124, the cutters illustrated in figs. 33-63 are tapered as claimed.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 15, 16, 17 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheicher as in paragraph 6 above in view of Roelke (2,025,779).

Scheicher does not have support shaft of the cutter angled at approximately 96 degrees with respect to the drive shaft. However, attention is directed to Roelke reference, which discloses another drill apparatus having an universal joint 11 and more specific to figs. 11&12 and page 2, col. 1, lines 21-34. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Scheicher device by adding a universal joint in the manner taught by Roelke in order to position the handle in a range of 0-10 degrees with relates to a 90-100 degree range between the cutter shaft and drive shaft for the convenience of the user in specific applications.

***Allowable Subject Matter***

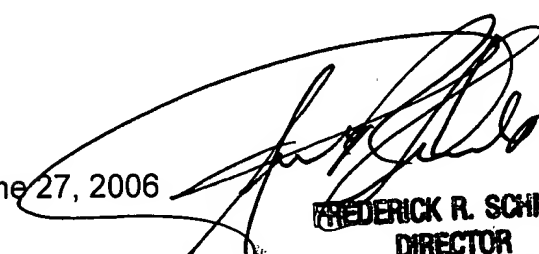
9. Claims 34, 91 and 108 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Claims 126, 127 and 129 are allowed.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LIEN TM NGO whose telephone number is 571-272-4545. The examiner can normally be reached on Monday through Friday from 8:30 AM -6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, KEVIN SHAVER can be reached on 571-272-4720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

June 27, 2006

  
**FREDERICK R. SCHMIDT**  
**DIRECTOR**  
**TECHNOLOGY CENTER 8700**

LIEN TM NGO  
Primary Examiner  
Art Unit 3754

